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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/037,460	03/10/1998	GREGG A. HASTINGS	325800-626(P)	7163

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HUMAN GENOME SCIENCES INC  
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ROCKVILLE, MD 20850

EXAMINER
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SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/037,460**

Applicant(s)  
**HASTINGS et al.**

Examiner  
**Christine Saoud**

Art Unit  
**1647**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 16, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 54-67, 75-92, 102-107, 115-119, and 122-175 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-67, 75-92, 102-107, 115-119, and 122-175 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 December 2002 has been entered.
2. Claims 54-67, 75-92, 102-107, 115-119, and 122-175 are pending in the instant application.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed 16 December 2002 have been fully considered but they are not deemed to be persuasive.

***Comments regarding Applicant's After-Final Submission***

6. Applicant asserts that the Aikenhead reference should have been considered in the previous response of 15 October 2002. Applicant is correct; the Examiner mistakenly looked at the date of entry of the previous response rather than the date of receipt of the response of paper #32. Applicant argues at page 3 of the response that the Examiner raised a new issue in the Final rejection of paper #35. This argument is not persuasive because the Examiner was merely addressing the new evidence of Applicant (namely, the Bechard reference), and therefore, this issue was not raised by the Examiner, but by the Applicant in the submission of the Bechard reference. It seems as if Applicant is questioning the finality of the previous Office action. However, in light of the filing of the current RCE, this argument is moot.

***Claim Rejections - 35 USC § 101***

7. Claims 54-67, 75-92, 102-107, 115-119 and 122-175 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record in paper #20, 24, 31 and 35. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

Applicant asserts that the specification teaches several "specific and substantial utilities for VIGF" including use as a diagnostic marker for tumors. This argument is not persuasive because the instant specification fails to teach which tumors the claimed invention would be useful for as a

diagnostic. There is no evidence or showing on record which would indicate that the claimed invention would prove useful in diagnosing tumors in any patient population. Furthermore, the instant specification fails to teach which population, if any, could be diagnosed with the claimed invention.

Applicant asserts at page 4 of the response that Aitkenhead et al. demonstrates that “VIGF is useful as a marker for angiogenesis and carcinomas”. This is not persuasive for a number of reasons. First, Aitkenhead shows that the claimed protein was upregulated in several renal cell carcinomas, but “expression appeared to be somewhat higher in normal tissue in other samples” (see page 165, column 2, lines 6-9). Second, Aitkenhead states that while ESM-1 expression correlates strongly with the degree of vascularity, “the precise role of ESM-1 in this process and the mechanistic relationship” is not known. Lastly, Aitkenhead concludes by stating that not all tumors upregulate ESM-1, that ESM-1 may be a target of VEGF or it may be an independent marker of tumor angiogenesis in some tissues. Therefore, based on the teachings of Aitkenhead et al., the skilled artisan would reasonably conclude that ESM-1 (VIGF of the instant application) may be a marker for renal tumors, but that it is not a reliable diagnostic for cancer in general. Additionally, while it is suggestive that ESM-1 may play a role in vascularization and that it may interact or be a target of VEGF, its role in angiogenesis is yet to be determined.

The instant specification fails to suggest the use of the claimed invention for diagnosis of renal tumors. The use for diagnosis of renal tumors would be specific, substantial and credible, but the instant specification fails to assert this utility. Use of the claimed invention for diagnosis of cancer in general is not credible based on the disclosure of Aitkenhead et al. This is further

complicated by Bechard et al. which teaches that septic patients have elevated ESM-1. Applicant asserts that “levels of VIGF in septic patients are not relevant to cancer diagnosis”. This is not persuasive because the fact that VIGF is elevated in other conditions suggests that the elevation of VIGF could indicate a number of different conditions and therefore, would cloud any potential diagnosis of cancer based on elevated VIGF alone. However, as stated above, VIGF does not correlate to cancer in general, and therefore, is not useful in diagnosis of cancer in general, as asserted by the instant specification.

Applicant points to Bechard et al. as demonstrating an elevation of endocan (i.e. VIGF) in patients with lung tumors. However, the instant specification fails to assert the utility of diagnosing lung tumors, which is a specific, substantial and credible utility. Applicant argues at page 5 of the response that a correlation between angiogenesis and cancer is well established at the time of the instant application. However, the association of a protein with angiogenesis alone does not make it a cancer diagnostic. There are a number of proteins which are involved in normal physiological processes which are not markers for diseases of those physiological processes. As pointed out in the references, VIGF is expressed to a greater extent in some normal tissues as well as in other disease processes. Therefore, the instant application fails to provide a specific, substantial and credible utility for the claimed invention.

8. Claims 54-67, 75-92, 102-107, and 115-119, and 122-175 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those

reasons given above with regard to the rejection of these claims under 35 U.S.C. §101 for the reasons of record in papers #20, 24, 27 and 35.

Applicant argues that because the invention has utility, then this rejection should be withdrawn as well. This argument is not persuasive for the reasons provided above, and therefore, is maintained.

### *Conclusion*

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*